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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,255	08/20/2002	David Wallach	WALLACH=28	2930

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BROWDY AND NEIMARK, P.L.L.C.  
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WASHINGTON, DC 20001-5303

EXAMINER

SCHULTZ, JAMES

ART UNIT PAPER NUMBER

1635

DATE MAILED: 08/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/070,255

Applicant(s)

WALLACH ET AL.

Examiner

J. D. Schultz, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 September 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-7, 10-13, 30, and 33 in part, drawn to a DNA sequence encoding the protein IREN, and to vectors, cells and pharmaceutical compositions thereof.

Group 2, claim(s) 1-7, 10-13, 30, and 32 in part, drawn to a DNA sequence encoding the protein IREN-10B, and to vectors, cells and pharmaceutical compositions thereof.

Group 3, claim(s) 1-7, 10-13 and 30 in part, drawn to a DNA sequence encoding the protein IREN-E, and to vectors, cells and pharmaceutical compositions thereof.

Group 4, claim(s) 6-13, drawn to a DNA sequence as depicted in figure 6, and cells, and vectors thereto.

Group 5, claim(s) 14, 16, 29, and 33, in part, drawn to a protein sequence encoding an IREN protein.

Group 6, claim(s) 14, 15, 29, 32, and 35 in part, drawn to a DNA sequence encoding the protein IREN-10B.

Group 7, claims 14, 16, 17, 29, and 36, in part, drawn to a protein sequence as depicted in figure 6.

Group 8, claim 19, drawn to antibodies specific for the IREN protein.

Group 9, claims 20, 37, and 39, drawn to a method of mediating the activity of NF-KappaB comprising administration of the IREN protein.

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Group 10, claims 20-22, 28, 37, and 38, drawn to methods of modulating the activity of NF-KappaB in cells comprising delivering the cDNA encoding said IREN, wherein said delivery is accomplished optionally by viral vector delivery.

Group 11, claims 23, and 28, drawn to a method of modulating TRAF2 mediated events comprising delivering antibodies directed to IREN.

Group 12, claims 24, 25 and 28, drawn to methods of modulating TRAF2 mediated events comprising delivery of an antisense directed to IREN.

Group 13, claims 26 and 28, drawn to methods of modulating TRAF2 mediated events comprising delivering a ribozyme directed to an IREN mRNA.

Group 14, claims 27, 28, 40, and 41, directed to methods of isolating and identifying molecules that bind directly to TRAF2, comprising the use of a yeast two-hybrid procedure.

Group 15, claim 31, drawn to a pharmaceutical composition comprising an antisense oligonucleotide directed to the IREN mRNA.

Group 16, claim 32 in part, drawn to any molecule to which an IREN-10B protein binds.

Group 17, claims 33 and 34 in part, drawn to any molecule to which an IREN protein binds.

Group 18, claim 42, drawn to a method of screening for ligands capable of binding to amino acid residues 225-501 of TRAF2.

Group 19, claims 43, and 44 in part, drawn to a method of screening for ligands capable of binding to the portion of the IREN sequence depicted in figure 6.

Group 19, claims 45 and 46 in part, drawn to a method for identifying and producing ligands capable of modulating the activity of the IREN protein.

Group 20, claim 46 in part, drawn to a method for identifying and producing ligands capable of modulating the activity of the IREN protein.

Group 21, claim 46 in part, drawn to a method for identifying and producing ligands capable of modulating the activity of the IREN-10B protein.

Group 22, claim 46 in part, drawn to a method for identifying and producing ligands capable of modulating the activity of a protein that binds to amino acid residues 225-501 of TRAF2.

The inventions listed as Groups 1-22 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

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According to the guidelines in Section (f)(i)(a) of Annex B of the PCT Administrative Instructions, the special technical feature as defined by PCT Rule 13.2 shall be considered to be met when all the alternatives of a Markush-group are of similar nature. For chemical alternatives, such as the claimed sequences, and their methods of use, the Markush group shall be regarded as being of similar nature when

- (A) all alternatives have a common property or activity and
- (B)(1) a common structure is present, i.e, a significant structure is shared by all of the alternatives or
- (B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to an art recognized class of compounds in the art to which the invention pertains.

The instant sequences are considered to be each separate inventions for the following reasons:

The sequences do not meet the criteria of (B)(1), as they do not share, one with another, a common core structure, as evidenced by the fact that each polynucleotide has its own unique sequence. Accordingly; the group drawn to the use of IREN mRNA or protein are not considered to share unity with any other group drawn to IREN-10B or IREN-E. Because unity of invention between the sequences is lacking and each sequence claimed is considered to constitute a special technical feature, each method of use or manufacture is also considered to have its own special technical feature and therefore be separate from all other claimed methods.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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### *Conclusion*

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz, Ph.D. whose telephone number is 571-272-0763. The examiner can normally be reached on 8:00-4:30 M-F.

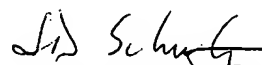
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

JD Schultz, PhD

  
**J.D. SCHULTZ, Ph.D.**  
**PATENT EXAMINER**